Response to Office Action of: 05/19/2006
Response Dated: 08/21/2006
Title: Custom Prosthetic Liner Manufacturing System And Method

App. No.: 10/724,526
Inventor: R. Arbogast et al.
Examiner: Charles R. Kasenge

Amendment(s) to the Claims

The following listing of claims replaces all prior versions and listings of claims in the present application:

Listing of Claims:

Claims 1-68 (canceled).

Claim 69 (currently amended): The method of claim 68 73, wherein said shape capture apparatus employs a plurality of spaced-apart image detectors.

Claim 70 (currently amended): The method of claim 68 73, wherein said storage means stores said data associated with the captured 3-dimensional shape of an amputee's residual limb on a machine readable medium for subsequent delivery to said facility equipped to produce said custom liner.

Claim 71 (currently amended): The method of claim 68 73, wherein said data associated with the captured 3-dimensional shape of an amputee's residual limb is remotely transmitted to said facility equipped to produce said custom liner.

Claim 72 (currently amended): The method of claim 68 73, wherein said data associated with the captured 3-dimensional shape of an amputee's residual limb is transmitted to said facility equipped to produce said custom liner over a local area network (LAN) or wireless local area network (WLAN).

Claim 73 (currently amended): ~~The method of claim 68, further comprising~~ A method of producing a custom flexible polymeric prosthetic liner, comprising:

using a shape capture apparatus to capture the 3-dimensional shape of an amputee's residual limb;

Response to Office Action of: 05/19/2006
Response Dated: 08/21/2006
Title: Custom Prosthetic Liner Manufacturing System And Method

App. No.: 10/724,526
Inventor: R. Arbogast et al.
Examiner: Charles R. Kasenge

providing a processing device in communication with said shape capture apparatus, said processing device for generating a 3-dimensional electronic model of said residual limb from said 3-dimensional shape captured by said shape capture apparatus;

providing a storage means in communication with said shape capture apparatus for temporarily storing data associated with said 3-dimensional shape of an amputee's residual limb;

providing a means of furnishing said data to a facility equipped to produce said custom prosthetic liner;

providing a means at said facility for associating prosthetic liner parameters with said data;

creating at least one custom mold component from said data associated with said 3-dimensional shape of an amputee's residual limb and said prosthetic liner parameters;

providing a mold for receiving and containing an amount of flexible polymeric material, said mold incorporating said at least one custom mold component; and

using a molding machine to produce said custom prosthetic liner from said mold;

Response to Office Action of: 05/19/2006
Response Dated: 08/21/2006
Title: Custom Prosthetic Liner Manufacturing System And Method

App. No.: 10/724,526
Inventor: R. Arbogast et al.
Examiner: Charles R. Kasenge

Claim 74 (currently amended): The method of claim 68 73, wherein said processing device consists of a computer program in combination with a device selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

Claim 75 (currently amended): The method of claim 68 73, further comprising a means for generating numerical data representative of said 3-dimensional model.

Claim 76 (original): The method of claim 75, wherein said numerical data is generated after delivery of said data associated with the captured 3-dimensional shape of an amputee's residual limb to said facility equipped to produce said custom liner.

Claim 77 (original): The method of claim 75, wherein said numerical data is generated by said shape capture apparatus or a device in communication with said shape capture apparatus, and said numerical data is subsequently provided to said facility equipped to produce said custom liner.

Claim 78 (currently amended): The method of claim 68 73, wherein said at least one custom mold component is produced by a computer-controlled machining device.

Claim 79 (currently amended): The method of claim 68 73, wherein said at least one custom mold component is created from a closed-cell foam material.

Claim 80 (currently amended): The method of claim 68 73, wherein said at least one custom mold component is a mold core for use with a common mold cavity.

Claim 81 (original): The method of claim 80, wherein said mold cavity is selected based on its size.

Claim 82 (currently amended): The method of claim 68 73, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.

Response to Office Action of: 05/19/2006
Response Dated: 08/21/2006
Title: Custom Prosthetic Liner Manufacturing System And Method

App. No.: 10/724,526
Inventor: R. Arbogast et al.
Examiner: Charles R. Kasenge

Claim 83 (currently amended): The method of claim 68 73, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

Claim 84 (original): The method of claim 83, wherein said custom prosthetic liner is manufactured from a block copolymer material.

Claim 85 (currently amended): The method of claim 68 73, wherein a fabric covering is applied to an outer surface of said custom prosthetic liner during the liner manufacturing process.

Claim 86 (currently amended): The method of claim 68 73, further comprising the ability to manipulate the data associated with said 3-dimensional shape of an amputee's residual limb to accommodate particular features of said residual limb in said custom prosthetic liner.

Claim 87 (currently amended): The method of claim 68 73, further comprising providing the ability to select liner materials and material properties.

Claim 88 (currently amended): The method of claim 68 73, further comprising providing the ability to specify accessories to be included in/on said custom prosthetic liner.

Claim 89 (original): The method of claim 88, wherein the number, location, and orientation of said accessories may also be specified.

Claim 90 (original): The method of claim 88, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.

Claim 91 (original): The method of claim 90, wherein said additives include anti-microbial substances.

Response to Office Action of: 05/19/2006   App. No.: 10/724,526
Response Dated: 08/21/2006   Inventor: R. Arbogast et al.
Title: Custom Prosthetic Liner Manufacturing System And Method   Examiner: Charles R. Kasenge

Claim 92 (currently amended): The method of claim 68 73, further comprising a means of communication with an automated system for configuring and purchasing a medical device.

Claims 93-109 (canceled).

Claim 110 (previously presented): A system for producing a custom prosthetic liner that allows an amputee with a residual limb of changed shape and/or size to continue wearing an existing prosthetic socket, comprising:

a shape capture apparatus for capturing a 3-dimensional shape of said amputee's residual limb;

a shape capture apparatus for capturing a 3-dimensional shape of the interior of said existing prosthetic socket;

a processing device, said processing device running a computer program for generating a 3-dimensional electronic liner model by comparing the captured 3-dimensional shapes of said amputee's residual limb and said interior of said existing prosthetic socket, calculating a difference in size and/or shape between the outer surface of said residual limb and the interior surface of said existing prosthetic socket, and automatically adjusting the thickness of said liner model as needed to make up for said difference in size and/or shape;

an optional interface for allowing a user of said system to operate said computer program to view and modify a 3-dimensional electronic residual limb model if so desired;

Response to Office Action of: 05/19/2006
Response Dated: 08/21/2006
Title: Custom Prosthetic Liner Manufacturing System And Method

App. No.: 10/724,526
Inventor: R. Arbogast et al.
Examiner: Charles R. Kasenge

a means of providing data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to a manufacturing facility equipped to produce said custom prosthetic liner;

an apparatus for creating at least one custom mold component from said data; and

a molding machine for producing said custom prosthetic liner from a mold incorporating said at least one custom mold component.

Claim 111 (original): The system of claim 110, wherein said shape capture apparatus for capturing the 3-dimensional shape of said residual limb is also used to capture the 3-dimensional shape of the interior of said existing prosthetic socket.

Claim 112 (original): The system of claim 110, wherein said processing device consists of a device selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

Claim 113 (original): The system of claim 110, wherein said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is provided to said manufacturing facility via the Internet.

Claim 114 (original): The system of claim 110, wherein said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is transmitted to said manufacturing facility over a local area network (LAN) or wireless local area network (WLAN).

Response to Office Action of: 05/19/2006
Response Dated: 08/21/2006
Title: Custom Prosthetic Liner Manufacturing System And Method

App. No.: 10/724,526
Inventor: R. Arbogast et al.
Examiner: Charles R. Kasenge

Claim 115 (original): The system of claim 110, further comprising a storage means for temporarily storing data associated with the shape of said residual limb and said 3-dimensional electronic liner model.

Claim 116 (original): The system of claim 115, wherein said storage means is selected from the group consisting of a hard disk, a floppy disk, a compact disc or other optical medium, a magneto-optical disk, a magnetic tape, and a PROM or similar other magnetic chip.

Claim 117 (original): The system of claim 110, further comprising a transmission device for remotely transmitting said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to said manufacturing facility.

Claim 118 (original): The system of claim 117, wherein said transmission device is selected from the group consisting of a dial-up modem, a DSL or ISDN modem, a cable modem, a WiFi card, a Bluetooth® card, a WCDMA card, a network interface card (NIC), or a wireless networking card.

Claim 119 (original): The system of claim 110, wherein said at least one custom mold component is a mold core for use with a common mold cavity.

Claim 120 (original): The system of claim 110, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.

Claim 121 (original): The system of claim 110, wherein said computer program also generates a viewable 3-dimensional electronic model of said existing prosthetic socket interior.

Response to Office Action of: 05/19/2006
Response Dated: 08/21/2006
Title: Custom Prosthetic Liner Manufacturing System And Method

App. No.: 10/724,526
Inventor: R. Arbogast et al.
Examiner: Charles R. Kasenge

Claim 122 (original): The system of claim 110, further comprising the ability to use said computer program to select liner materials and liner material properties.

Claim 123 (original): The system of claim 110, further comprising the ability to use said computer program to specify accessories to be included in/on said custom prosthetic liner.

Claim 124 (original): The system of claim 123, wherein the number, location, and orientation of said accessories may also be specified.

Claim 125 (original): The system of claim 123, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.

Claim 126 (original): The system of claim 125, wherein said additives include anti-microbial substances.

Claim 127 (original): The system of claim 110, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

Claim 128 (original): The system of claim 127, wherein said custom prosthetic liner is manufactured from a block copolymer material.

Claim 129 (previously presented): A system for producing a custom prosthetic liner that allows the residual limb of an amputee to be custom fit to a generic prosthetic socket, comprising:

 a shape capture apparatus for capturing the 3-dimensional shape of an amputee's residual limb;

 socket data representative of the 3-dimensional shape of an interior of ~~said~~ a generic prosthetic socket;

Response to Office Action of: 05/19/2006
Response Dated: 08/21/2006
Title: Custom Prosthetic Liner Manufacturing System And Method

App. No.: 10/724,526
Inventor: R. Arbogast et al.
Examiner: Charles R. Kasenge

a processing device, said processing device running a computer program for generating a 3-dimensional electronic liner model by comparing the captured 3-dimensional shape of said amputee's residual limb and said interior of said generic prosthetic socket, calculating a difference in size and/or shape between the outer surface of said residual limb and said interior surface of said generic prosthetic socket, and automatically adjusting the thickness of said liner model as needed to make up for said difference in size and/or shape;

an optional interface for allowing a user of said system to operate said computer program to view and modify a 3-dimensional electronic residual limb model if so desired;

a means of providing data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to a manufacturing facility equipped to produce said custom prosthetic liner;

an apparatus for creating at least one custom mold component from said data; and

a molding machine for producing said custom prosthetic liner from a mold incorporating said at least one custom mold component.

Claim 130 (original): The system of claim 129, wherein said socket data is available as a result of the socket manufacturing process.

Claim 131 (original): The system of claim 129, wherein said socket data is obtained by capturing the 3-dimensional shape of the interior of said generic prosthetic socket.

Response to Office Action of: 05/19/2006
Response Dated: 08/21/2006
Title: Custom Prosthetic Liner Manufacturing System And Method

App. No.: 10/724,526
Inventor: R. Arbogast et al.
Examiner: Charles R. Kasenge

Claim 132 (original): The system of claim 129, wherein said shape capture apparatus for capturing the 3-dimensional shape of said residual limb is also used to capture the 3-dimensional shape of the interior of said generic prosthetic socket.

Claim 133 (original): The system of claim 129, wherein said generic socket is preselected from a group of generic prosthetic sockets, based on its size.

Claim 134 (original): The system of claim 129, wherein said processing device consists of a device selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

Claim 135 (original): The system of claim 129, wherein said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is provided to said manufacturing facility via the Internet.

Claim 136 (original): The system of claim 129, wherein said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is transmitted to said manufacturing facility over a local area network (LAN) or wireless local area network (WLAN).

Claim 137 (original): The system of claim 129, further comprising a storage means for temporarily storing data associated with the shape of said residual limb and said 3-dimensional electronic liner model.

Claim 138 (original): The system of claim 129, wherein said storage means is selected from the group consisting of a hard disk, a floppy disk, a compact disc or other optical medium, a magneto-optical disk, a magnetic tape, and a PROM or similar other magnetic chip.

Response to Office Action of: 05/19/2006
Response Dated: 08/21/2006
Title: Custom Prosthetic Liner Manufacturing System And Method

App. No.: 10/724,526
Inventor: R. Arbogast et al.
Examiner: Charles R. Kasenge

Claim 139 (original): The system of claim 129, further comprising a transmission device for remotely transmitting said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to said manufacturing facility.

Claim 140 (original): The system of claim 129, wherein said transmission device is selected from the group consisting of a dial-up modem, a DSL or ISDN modem, a cable modem, a WiFi card, a Bluetooth® card, a WCDMA card, a network interface card (NIC), or a wireless networking card.

Claim 141 (original): The system of claim 129, wherein said at least one custom mold component is a mold core for use with a common mold cavity.

Claim 142 (original): The system of claim 129, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.

Claim 143 (original): The system of claim 129, further comprising a separate system and computer program for facilitating the automatic configuration and purchasing of a medical device, said separate system and computer program accessible via said processing device.

Claim 144 (original): The system of claim 143, wherein said generic socket may be selected from a database of said system and computer program for facilitating the automatic configuration and purchasing of a medical device.

Claim 145 (original): The system of claim 129, wherein said computer program also generates a viewable 3-dimensional electronic model of said generic prosthetic socket interior.

Response to Office Action of: 05/19/2006
Response Dated: 08/21/2006
Title: Custom Prosthetic Liner Manufacturing System And Method

App. No.: 10/724,526
Inventor: R. Arbogast et al.
Examiner: Charles R. Kasenge

Claim 146 (original): The system of claim 129, further comprising the ability to use said computer program to select liner materials and liner material properties.

Claim 147 (original): The system of claim 129, further comprising the ability to use said computer program to specify accessories to be included in/on said custom prosthetic liner.

Claim 148 (original): The system of claim 147, wherein the number, location, and orientation of said accessories may also be specified.

Claim 149 (original): The system of claim 147, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.

Claim 150 (original): The system of claim 149, wherein said additives include anti-microbial substances.

Claim 151 (original): The system of claim 129, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

Claim 152 (original): The system of claim 151, wherein said custom prosthetic liner is manufactured from a block copolymer material.

Claims 153-186 (canceled).

Claim 187 (currently amended): ~~The method of claim 186,~~ A method of producing a custom flexible polymeric prosthetic liner, comprising:

> obtaining shape data associated with an amputee's residual limb;
>
> providing a processing device in conjunction with a computer program for generating a 3-dimensional electronic liner model from said shape data and liner parameters input by a user of said system;

Response to Office Action of: 05/19/2006
Response Dated: 08/21/2006
Title: Custom Prosthetic Liner Manufacturing System And Method

App. No.: 10/724,526
Inventor: R. Arbogast et al.
Examiner: Charles R. Kasenge

optionally, providing an interface for allowing a user of said system to operate said computer program to view and modify a 3-dimensional electronic residual limb model if so desired, data associated with said residual limb model subsequently used in generating said liner model;

providing data associated with said residual limb shape, said 3-dimensional electronic liner model, or both, to a manufacturing facility equipped to produce said custom liner;

creating at least one custom mold component from said data;

providing a mold for receiving and containing an amount of flexible polymeric material, said mold incorporating said at least one custom mold component; and

using a molding machine to produce said custom prosthetic liner from said mold;

wherein said shape data is obtained from ~~an existing~~ a cast of said residual limb.

Claim 188 (currently amended): The method of claim ~~186~~ 187, wherein said shape data is obtained by first producing a cast of said residual limb.

Claim 189 (original): The method of claim 188, further comprising electronically capturing a 3-dimensional image of an interior of said cast and providing electronic data associated therewith to said processing device.

Claim 190 (original): The method of claim 189, wherein said image capturing is done at said manufacturing facility.

Response to Office Action of: 05/19/2006
Response Dated: 08/21/2006
Title: Custom Prosthetic Liner Manufacturing System And Method

App. No.: 10/724,526
Inventor: R. Arbogast et al.
Examiner: Charles R. Kasenge

Claim 191 (original): The method of claim 190, wherein said cast is sent to said manufacturing facility.

Claim 192 (currently amended): The method of claim ~~186~~ 187, wherein said shape data is obtained by producing measurements of said residual limb.

Claim 193 (original): The method of claim 192, further comprising entering said measurements into said system for use by said processing device.

Claim 194 (currently amended): The method of claim ~~186~~ 187, wherein said processing device is selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

Claim 195 (currently amended): The method of claim ~~186~~ 187, wherein data associated with the shape of said residual limb, said 3-dimensional electronic liner model, or both, is stored on a machine readable medium and is manually delivered to said facility equipped to produce said custom liner.

Claim 196 (currently amended): The method of claim ~~186~~ 187, wherein data associated with the shape of said residual limb, said 3-dimensional electronic liner model, or both, is remotely transmitted to said facility equipped to produce said custom liner.

Claim 197 (currently amended): The method of claim ~~186~~ 187, wherein data associated with the shape of said residual limb, said 3-dimensional electronic liner model, or both, is transmitted to said facility equipped to produce said custom liner over a local area network (LAN) or wireless local area network (WLAN).

Claim 198 (currently amended): The method of claim ~~186~~ 187, wherein said at least one custom mold component is produced from said data.

Response to Office Action of: 05/19/2006
Response Dated: 08/21/2006
Title: Custom Prosthetic Liner Manufacturing System And Method

App. No.: 10/724,526
Inventor: R. Arbogast et al.
Examiner: Charles R. Kasenge

Claim 199 (currently amended): The method of claim ~~186~~ 187, wherein said at least one custom mold component is created from a closed-cell foam material.

Claim 200 (currently amended): The method of claim ~~186~~ 187, wherein said at least one custom mold component is a mold core for use with a common mold cavity.

Claim 201 (original): The method of claim 200, wherein said mold cavity is selected based on its size.

Claim 202 (currently amended): The method of claim ~~186~~ 187, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.

Claim 203 (currently amended): The method of claim ~~186~~ 187, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

Claim 204 (original): The method of claim 203, wherein said custom prosthetic liner is manufactured from a block copolymer material.

Claim 205 (currently amended): The method of claim ~~186~~ 187, wherein a fabric covering is applied to an outer surface of said custom prosthetic liner during the liner manufacturing process.

Claim 206 (currently amended): The method of claim ~~186~~ 187, further comprising the ability to select liner materials and liner material properties.

Claim 207 (currently amended): The method of claim ~~186~~ 187, further comprising the ability to specify accessories to be included in/on said custom prosthetic liner.

Claim 208 (original): The method of claim 207, wherein the number, location, and orientation of said accessories may also be specified.

Response to Office Action of: 05/19/2006
Response Dated: 08/21/2006
Title: Custom Prosthetic Liner Manufacturing System And Method

App. No.: 10/724,526
Inventor: R. Arbogast et al.
Examiner: Charles R. Kasenge

Claim 209 (original): The method of claim 207, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.

Claim 210 (original): The method of claim 209, wherein said additives include anti-microbial substances.

Claim 211 (currently amended): The method of claim ~~186~~ <u>187</u>, further comprising a means of communication with an automated system for configuring and purchasing a medical device.